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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,353	05/30/2001	Yan Wang	020130-000111US	8319

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/870,353

Applicant(s)

WANG ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/10/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,17,20,22-30 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,17,20,22-30 and 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants filing of a brief in response to a final rejection on 10/28/2005, is acknowledged. Claims 15, 17, 20, 22-30 and 32-42 are pending and at issue.

Applicants' arguments filed on 10/10/2006, have been fully considered and are not deemed to be persuasive to overcome the rejections previously applied. Upon further consideration a number of references not previously made of record have been included in the rejection. It is for this reason that prosecution is hereby re-opened. Any inconvenience to applicant is regretted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 17, 20, 22-30 and 32-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein comprising two heterologous domains wherein the first domain is a sequence-non-specific-double-stranded nucleic-acid-binding domain joined to a second domain which is a DNA polymerase domain, wherein said sequence-non-specific-double-stranded nucleic-acid-binding domain is selected from the group consisting of Sso7d or Sac7d, does not reasonably provide enablement for any protein comprising two heterologous domains wherein the first domain is a sequence-non-specific-double-stranded nucleic-acid-binding domain joined to a second domain which is a DNA polymerase domain, wherein

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said sequence-non-specific-double-stranded nucleic-acid-binding domain comprises an amino acid sequence that has at least 75% sequence identity to SEQ ID NO: 2 or said sequence-non-specific-double-stranded nucleic-acid-binding domain comprises an amino acid sequence that has at least 75% identity to the Sac7d sequence set forth in SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 15, 17, 18, 20 and 22-42. In response to this rejection, applicants have filed a brief addressing this rejection. As stated above, a number of references not previously made of record in this application are being used in the current rejection and thus this has resulted in the re-opening of prosecution and those points made by applicants in their brief will be addressed.

Applicants continue to traverse this rejection as in their previous responses. Applicants submit that applicant's specification provides examples that show that both Sso7d and Sac7d increase processivity when joined to polymerases and directs the practitioner to the large body of art in this field that provides detailed structural insight into the interaction of Sso7d and Sac7d with DNA. Applicants continue to reference the Rule 132 Declaration by Dr. Peter Vander Horn and submit that the level of knowledge in this art is high and there is a large body of art in this field that provides detailed structural insight into the interaction of Sso7d protein with DNA. Applicants again reference as support of applicants position that Dr. Vander Horn has created a

hypothetical hybrid protein based on the sequences of Sso7d and Sso7d homologues Sac7d, Sac7e and Sac7a to derive a domain that has 76% identity to Sso7d and that applicants have provided examples in the specification showing that both Sso7d and its homologue Sac7d increase processivity when joined to polymerases.

Applicants complete argument is acknowledged, however, not found persuasive for the reasons previously stated and repeated below. It continues that the level of skill in the art is high, although applicants have not provided the guidance necessary to make the genus of proteins claimed, that encompasses those sequence non-specific double-stranded nucleic acid binding domains having a mere 75% sequence identity to the amino acid sequence of SEQ ID NO: 2. While applicants have submitted that applicants have created a hypothetical protein that has 76% identity to Sso7d, based on the sequences of Sso7d and its homologues, this hypothetical protein is but a single species of the multitude of claimed proteins and does not provide the necessary guidance for the construction of the genus of proteins that function as a sequence non-specific double-stranded nucleic acid binding domain, but that further enhances the processivity of a joined polymerase domain.

Applicants limited guidance in light of the state and unpredictability of the art leads to the lack of enablement of the claimed genus. Such unpredictability of the prior art is evidenced by the following.

The prior art teaches that single point mutations of Sso7d (98% similar sequence to Sso7d) will affect the function of the nucleic acid binding domain and renders the art unpredictable. Applicant's own post filing art, Wang et al. (Wang et al., Nucleic Acids

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Research, 2004, vol. 32, p 1197-1207), teach the finding that mutational changes in Trp24 of Sso7d significantly reduce its effectiveness in enhancing processivity. Wang et al. further states that the use of a DNA binding protein with a much higher affinity for dsDNA could be detrimental to the catalytic activity of the polymerase and teach that further studies are needed to identify the optimal range of affinities of the dsDNA binding protein to achieve the ultimate balance between processivity and catalysis (page 1205, 1st full paragraph). Shehi et al. (Biochemistry, 2003, vol 42, pp. 8362-8) teach the deletion of Glu53 in Sso7d could not be isolated and suggests that this mutation misfolds the protein and deletion Leu54 in Sso7d has limited solubility in aqueous solution (page 8364, 2nd column, 1st full paragraph). Both mutations demonstrate the unpredictability of the effect of point mutations in Sso7d on any particular function or attribute of Sso7d. Finally, Consonni et al. (Biochemistry, 1999, vol 38, pp 12709-17) teach the mutation of F31A and W23A in Sso7d impairs the capacity of the protein to bind dsDNA. The art specifically teaches that sequence similarity alone does not necessarily provide a predictable correlation between the structure and specific function of a protein. Neither the art nor the specification teach what other domains, regions, or specific amino acids of Sso7d are responsible for sequence non-specific dsDNA binding or enhancing processivity of an attached polymerase. The prior art supports the unpredictability of this area of technology.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein comprising two heterologous

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domains wherein the first domain is a sequence-non-specific-double-stranded nucleic-acid-binding domain joined to a second domain which is a DNA polymerase domain, wherein said sequence-non-specific-double-stranded nucleic-acid-binding domain comprises an amino acid sequence that has at least 75% sequence identity to SEQ ID NO: 2 or said sequence-non-specific-double-stranded nucleic-acid-binding domain comprises an amino acid sequence that has at least 75% identity to the Sac7d sequence set forth in SEQ ID NO: 10. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 6:30 am-3:00 pm, M--F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rg
10/21/2005


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